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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,674	11/13/2003	Ken Y. Lin	STAN-276	9855

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EXAMINER
VENCI, DAVID J

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/713,674	Applicant(s) LIN ET AL.	
	Examiner David J. Venci	Art Unit 1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED January 18, 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s):

   Claim 1 rejection pursuant to 35 U.S.C. 112, second paragraph, phrase "said sample comprises ADMA and at least one of SDMA and arginine"..
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *1-9,15 and 17-19*.
   Claim(s) withdrawn from consideration: *none*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

LONG V. LE 02/16/07
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Continuation of 11:

Applicants' argumentation does not enable Applicants' claimed invention. Furthermore:

1) Applicants' specification does not enable the claimed two-step method.

At most, Applicants' specification teaches extracting an unidentified "sample" and an unidentified "internal standard", followed by an unidentified *o*-phthaldialdehyde derivatization procedure, followed by a vague "α-dicarbonyl" derivatization procedure[1], and concluding with HPLC isolation and detection of an unidentified "analyte" (see paragraphs [0047] and [0048]). Examiner posits that the aforementioned information is not enabling of any method, much less the claimed two-step method (*i.e.*, a homogeneous assay) comprising the steps of: a) contacting a sample with an a-dicarbonyl compound, followed by b) detecting ADMA in the sample.

2) None of Applicants' listed prior art techniques describe a means for detecting ADMA in a two-step method.

At most, Applicants disclose a means for detecting a hypothetical "analyte" by HPLC ***after*** extracting an unidentified "sample" and an unidentified "internal standard", derivatizing with an unidentified *o*-phthaldialdehyde derivatization procedure, followed by derivatizing with a vague "α-dicarbonyl" derivatization procedure[2] (see paragraphs [0047] and [0048]). Given the aforementioned deficiencies in Applicants' disclosure, Examiner posits that, even with the help and knowledge of prior art teachings, the quantity of experimentation needed to detect ADMA in Applicants' claimed two-step method is undue.

3) Applicants supposedly invented a method enabling ***any*** α-dicarbonyl compound in a two-step method.

Examiner has uncovered 242,619 searchable compounds falling within Applicants' definition of an "α-dicarbonyl" compound. Applicants' method does not enable a single one of these 242,619 compounds in the claimed two-step method.

4) The cited prior art provide evidence that not all α-dicarbonyl compounds are useful in two-step methods.

The cited prior art establishes the indiscriminant, unpredictable behavior of certain α-dicarbonyl compounds with respect to modification of both (a) analytes and (b) non-analytes. The cited prior art establishes that such indiscriminant, unpredictable behavior will negatively impact homogeneous assays, which require ascertainable and predictable modification of both (a) XOR (b).

Examiner maintains all other rejections for reasons of record.

[1] Applicants provide minimal information of such a procedure in paragraph [0098], which discloses a derivatization of an unidentified sample with phenylglyoxal dissolved in water, pH 9.0, in the dark at room temperature for 60-180 minutes.

[2] *Id.*